

REMARKS

In the instant Action, Claims 1-27 are listed as pending, of which Claims 6-10 and 12-27 are listed as withdrawn from consideration, and Claims 1-5 and 11 are listed as rejected.

Firstly, it is not immediately apparent as to why Claims 6-10 are listed as withdrawn. For the time being, Applicant has not used the status identifier “Withdrawn” for Claims 6-10. In the Restriction Requirement set forth in the last Office Action, mailed 01/12/2009, the Examiner required restriction to one of the following inventions:

- I) Claims 1-12, drawn to compounds.
- II) Claims 13-15, drawn to methods of using compounds.
- III) Claims 16-24, drawn to compounds.
- IV) Claims 25-27, drawn to methods of using compounds.

In Applicant’s last response, filed 02/06/2009, Applicant elected the invention of Group I, represented by Claims 1-12. As such, Applicant respectfully request that the Examiner examine Claims 6-10 on their merits, or alternatively, explicitly provide the Examiner’s reason for listing Claims 6-10 as withdrawn from consideration.

On the other hand, and consistent with the Examiner’s Restriction Requirement, Applicant used the status identifier “Withdrawn” for Claims 13-15, which are eligible for rejoinder in the event that any of Claims 2-12 are found to be patentable.

Further consistent with the Examiner’s Restriction Requirement, Applicant has canceled Claims 16-27, which are drawn to non-elected inventions, so as to place this application in a condition for allowance.

Response to issues presented under nonstatutory obviousness-type double patenting

Claim 1 is rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claim 1 of U.S. Patent No. 6,903,186, or claim 1 of U.S. Patent No. 7,521,527, or claim 1 of U.S. Patent No. 6,903,186, or claim 1 of U.S. Patent No. 7,268,213. Without addressing the substantive merits *vel non* of this rejection, but solely in order to place the instant application in a

condition for allowance, Applicant has canceled Claim 1. In view thereof, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Response to issues presented under 35 U.S.C. §102

Claim 1 is rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Buckley (U.S. Patent No. 5,545,618). Without addressing the substantive merits *vel non* of this rejection, but solely in order to place the instant application in a condition for allowance, Applicant has canceled Claim 1. In view thereof, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Response to issues presented under 35 U.S.C. §103

Claim 1 is rejected under 35 U.S.C. §103 as allegedly being unpatentable over Buckley (U.S. Patent No. 5,545,618). Without addressing the substantive merits *vel non* of this rejection, but solely in order to place the instant application in a condition for allowance, Applicant has canceled Claim 1. In view thereof, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Response to issues presented under 35 U.S.C. §112, first paragraph

Claims 1-5 and 11 are rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In particular, Claims 1-5 and 11 are rejected on the basis that Applicant failed to provide data compiled using the assay protocol described in the specification evidencing the claimed compounds' ability to perform as asserted.

Without conceding the correctness of the stated rejection, Applicant submits herewith the Declaration of John E. Taylor, Ph.D., pursuant to Rule 132, introducing experimental data illustrating the claimed compounds' ability to perform as asserted. As such, there is sufficient basis for concluding that the claimed compounds of the instant application are capable of binding to the hGLP-1 receptor. On this basis alone, Applicant

respectfully submits that the Examiner's concerns regarding the utility of the claimed invention are adequately addressed.

With respect to the claimed compounds of the *genus* formula (I) of Claim 2, as amended, Applicant respectfully submits that a skilled artisan would readily be able to extrapolate the experimental data for all twenty-seven (27) compounds claimed in Claim 11 to the *other* claimed compounds encompassed by the *genus* formula (I) of Claim 2. According to MPEP §2164.03, the "predictability or lack thereof" in the art simply refers to "the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention".

In any case, it is apparent that it would not require "undue experimentation" for a skilled artisan to follow the same procedure as outlined in the instant application to obtain similar experimental data for the *other* claimed compounds encompassed by the *genus* formula (I) of Claim 2. In the absence of any indication in the instant Action that the disclosed assay would entail "undue experimentation," other than the alleged unpredictability in the art, Applicant submits that all of the claimed compounds of all pending claims are sufficient enabled; e.g., there is no objective indication that the skilled artisan would be unable to follow the disclosed assay without "undue experimentation."

In the instant Action, at page 3, the Examiner concludes that "undue experimentation" would be required to use the claimed compounds to displace (¹²⁵I)GLP-1(7-36) from RIN 5F rat insulinoma cells expressing the GLP-1 receptor, because "one cannot predict GLP receptor binding merely by viewing the structure of a compound." According to the Examiner's reasoning, even if a group of chemists follow the disclosed assay to synthesize and test a certain number of the claimed compounds as a routine part of normal pharmaceutical research, even then the skilled artisan would not be able to reliably "predict" that even one of those compounds would bind to the GLP-1 receptor. However, Applicant respectfully submits that if the skilled artisan is able to synthesize and test any one of the claimed compounds according to the disclosed assay – see, e.g., the Declaration of John E. Taylor, Ph.D., pursuant to Rule 132, introducing experimental data for all 27 compounds of Claim 11 – and if the skilled artisan is able to do so without "undue experimentation," then the skilled artisan is enabled to make and use the

compound without having to “predict” whether that compound would bind to the GLP-1 receptor. Applicant respectfully submits that there is no requirement under 35 U.S.C. §112, first paragraph, that the skilled artisan be able to “predict” whether the claimed compound would bind to the GLP-1 receptor when he/she would be expected to follow the disclosed assay to determine such activity.

As noted above, according to MPEP §2164.03, the “predictability or lack thereof” in the art simply refers to “the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention”, as it is a tautology to state that the skilled artisan would be unable to “predict” the claimed compound’s asserted utility because the art is generally unpredictable. The real question is whether Applicant has provided enough disclosure to enable the skilled artisan to make and use the claimed invention. It is unquestionable “undue experimentation” would not be required to make any one of the claimed peptides. With respect to the “how to use” prong of the enablement requirement, there is no objective basis to assert that following the disclosed assay protocol to test the claimed compounds’ activity would entail “undue experimentation.” On this alternative ground, aside from the submission of the Declaration of John E. Taylor, Ph.D., pursuant to Rule 132, introducing experimental data for all 27 compounds of Claim 11, Applicant respectfully requests reconsideration and withdrawal of this rejection under 35 U.S.C. §112, first paragraph.

Conclusion

In view of the remarks herein, Applicant respectfully requests that the rejections set forth in the instant Action be reconsidered and withdrawn and that this application be passed to issue. Prompt and favorable action is earnestly solicited.

Respectfully submitted,



Tony K. Uhm (Reg. No. 52,450)
Attorney for Applicant(s)

BIOMEASURE, INCORPORATED
27 Maple Street
Milford, MA 01757-3650
TEL.: (508) 478-0144
FAX: (508) 478-2530